K130426

NOV 19 2013

510(k) Summary
for the Sumitomo
Proton Therpay System
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

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Date Prepared: February 15, 2013

2. DEVICE NAME

Proprietary Name:	Sumitomo Proton Therapy System (PTS)
Common/Usual Name:	Proton Therapy System
Classification Name:	Medical charged-particle radiation therapy system

3. PREDICATE DEVICES

- M.D. Anderson Proton Therapy System (K053280)
- Northeast Proton Therapy Center/Mass. General Hospital (K983332)

4. DEVICE DESCRIPTION

The Sumitomo Proton Therapy System (PTS) is a large-scale medical electrical system that consists of an integrated system of medical electrical equipment and non-medical electrical components to provide proton beam radiation therapy.

The Sumitomo PTS consists of a 230 MeV Cyclotron, an Energy Selection System, a Beam Transport System, and a Gantry Treatment System.

5. INTENDED USE

The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The initial Sumitomo Proton Therapy System installed and commissioned includes a compact gantry and a multi-purpose nozzle. The single gantry system is expandable to a multi-gantry system. The multi-purpose nozzle provides both wobbling scanning function and pencil beam scanning function. The scope of this 510(k) submission is the wobbling scanning function only. The major PTS system features include:

- Cyclotron (230 MeV)
- Energy selection system
- Beam transport system
- Multipurpose Nozzle (Initially Wobbling Scanning only)
- Respiratory Gating System
- Multi Leaf Collimator
- Online PET (Gamma ray detector)
- Compact Gantry
- Patient Positioning System

A comparison was made to two predicate systems, the M.D. Anderson Proton Therapy System (K053280) manufactured by Hitachi Ltd. and the Northeast Proton Therapy Center (NPTC) (K983332) manufactured by IBA. The Sumitomo PTS system has the same of intended use, similar operating parameters and similar system features compared to the predicate systems. The proposed and predicate systems have a proton source, a synchrotron for the M.D. Anderson Center, and a cyclotron for the NPTC and the Sumitomo PTS. The radiation generated by the proton sources is then directed to gantries and into treatment rooms.

The operational characteristics of the proposed and predicated devices are similar. The accelerator energies are in the same range (70 to 250 MeV). The beam transport systems for all three devices deliver the accelerated protons to the gantries to be used for treatment. The gantries direct the radiation through treatment heads to patients. The treatment heads direct the radiation to treatment sites determined by treatment planning software. The operation of all three cited systems is the same with protons accelerated and directed to patients for safe and effective treatments.

The gantries in the Sumitomo PTS are of a compact design which saves space and resources without impacting effectiveness and safety. The gantries of the predicate devices are of a conventional size and design. The treatment heads mounted on the gantries are of similar design and allow various patterns of radiation for different treatments. Overall, the technological characteristics of all three cited systems are similar and allow for safe and effective treatments. The Sumitomo system will

include a gamma ray detector system (online PET) that uses technology based on the positron emission tomography (PET). The online PET system detects gamma ray emissions from two sides of the treated tumor to provide a projection image of the treated area. This system generates a limited spatial resolution image of original gamma ray source position by inverse calculation for confirming that the proton beam reached the intended tumor tissue. This PET system is used just after treatment and does not provide real-time control of the proton beam.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

A series of factory and on-site safety and performance studies were completed to assess the performance of the Sumitomo PTS. Testing was performed and documented to ensure the design outputs of the system and its components have met design specifications in a complete and verifiable manner. Testing was peformed at the unit level and subsystem level at the factory and on-site. Based on the extensive factory testing and on-site testing performed, the Sumitomo PTS system was found to meet all performance requirement specifications for hardware, software, and safety requirements for a proton therapy system.

The Sumitomo PTS met the requirements of all design specifications.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted or required in support of this premarket clearance notification.

9. SUMMARY OF OTHER INFORMATION

This submission includes comparison of intended use statements, proposed product labeling and summary information and labeling on predicate devices.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the information provided in this 510(k), Sumitomo believes that the proposed proton therapy system is substantially equivalent to the previously cleared Hitachi and IBA proton therapy systems. The Sumitomo PTS has the same intended use, similar design, principle of operation, and technological characteristics as its predicate devices. The minor technological difference between the Sumitomo PTS and its predicate devices is the compact gantry. The compact gantry uses similar principles to the predicate devices. The Sumitomo system also uses an online PET system that is used post treatment and does not provide real time control of the proton beam. The overall design of the proposed and predicate devices is similar. The

differences between these devices are limited to design modifications implemented to improve the convenience and ease of use of the proposed device. These design modifications are minor and raise no new issues of safety or effectiveness. Thus, the Sumitomo Proton Therapy System is substantial equivalent to the previously cleared predicate devices.

The proposed device raises no new issues of safety and effectiveness. The non-clinical safety and performance testing performed demonstrates that the proposed device met all test specifications and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Sumitomo Heavy Industries, Ltd.
% Mr. Ronald S. Warren
Director, Regulatory Services
11440 W. Bernardo Court, Suite 300
SAN DIEGO CA 92127

Re: K130426
Trade/Device Name: Sumitomo Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: October 29, 2013
Received: October 31, 2013

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130426

Device Name
Sumitomo Proton Therapy System

Indications for Use *(Describe)*
The Sumitomo Proton Therapy System is a medical device designed to produce and deliver a proton beam for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara